

Attorney Docket No.: PTQ-0027  
Inventors: Van Byk et al.  
Serial No.: 09/115,589  
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#### REMARKS

Claims 56-59, 62-69, 71-84 and 87-102 are pending in the instant application. Claims 99-102 have been withdrawn from consideration by the Examiner. Claims 56-59, 62-69, 71-84 and 87-98 have been rejected. Claims 56-59, 62-69 and 71-79 have been herein canceled without prejudice. Applicants reserve the right to pursue this canceled subject matter in a continuation application. Claims 80, 97, 99, 100, 101 and 102 have herein been amended. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### I. Restriction Requirement

Applicants thank the Examiner for reconsidering and withdrawing the Restriction Requirement of October 18, 2005.

With respect to the March 10, 2000 election referred to by the Examiner at page 3 of the Office Action, Applicants would like to clarify that this election of TnI and residues 1-193 of TnI was made in response to a species election requirement. Thus, in accordance with MPEP 809.01 and 37 C.F.R. 1.146, the claims should only be restricted to this species if no generic claim is held allowable. Applicants

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believe the amendments to the claims with the below arguments place generic claims in condition for allowance.

Further, reconsideration with respect to the Examiner's withdrawal of claims 99-102 is also respectfully requested in light of the arguments and amendments made herein which Applicants believe place in condition for allowance generic claims 80 and 97.

## II. Objection to Specification under 35 U.S.C. 132

The Examiner has maintained, in part, the objection under 35 U.S.C. 132 to the August 6, 2004 amendments to the specification. Specifically, the Examiner suggests that no compelling argument has been provided for entry of amendments to the specification at page 11, 12 and 14 to include the MLC1 rat sequence of 199 amino acids as SEQ ID NO:28 and the corresponding shorter human MLC1 sequences. The Examiner suggests that the amendment appears to be an attempt to obtain broader scope rather than correction of an obvious error.

Applicants respectfully disagree as this amendment was made merely to address the Examiner's concerns regarding clarification of sequence source, not broaden the claim scope.

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However, in earnest effort to advance the prosecution of this case, Applicants have amended the paragraphs at page 11 and 14 to conform to the originally filed specification with the exception of including a reference to the required sequence identifier SEQ ID NO:28 for this MLC1 fragment. Amendment to the paragraph at page 12 is not required as it conforms to the paragraph as originally filed.

Applicants are also providing herewith a replacement paper and CRF copy of the Sequence Listing removing any reference to SEQ ID NO:50 as well as the required statement in accordance with 37 C.F.R. 1.1821-1.825.

Withdrawal of this objection to the specification is respectfully requested.

III. Rejection of Claims 56-59, 62-65, 68-69, 71-84, 87-90 and 92-98 under 35 U.S.C. 102(b)

Claims 56-59, 62-65, 68-69, 71-84, 87-90 and 92-98 have been rejected under 35 U.S.C. 102(b) as being anticipated by Lofberg. Applicants respectfully traverse this rejection.

At the outset, without conceding in any way to this rejection, it is respectfully pointed out that claims 56-59, 62-65 and 71-79 have been canceled, without prejudice. Thus, this rejection as it pertains to these claims is now

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moot. Applicants reserve the right to pursue this subject matter in a continuation application.

Further, claims 80, 97 and 99-102 have been amended to state skeletal muscle damage and to specify skeletal peptide fragments in accordance with teachings throughout the specification. See, for example page 2, lines 20-25, page 4, lines 4-12, page 11, line 22, through page 12, line 3, page 12, lines 22-24, page 37-41 and Figures 11-14.

Accordingly, the pending claims are drawn to a method for assessing skeletal muscle damage in a subject, comprising detecting the presence or absence or measuring the amount of one or more of: (a) a peptide fragment of a myofilament protein; or (b) a covalent or non-covalent complex of at least: (i) a peptide fragment of a myofilament protein and an intact myofilament protein; or (ii) two peptide fragments of myofilament proteins, in a biological sample obtained from a subject being assessed for skeletal muscle damage wherein the peptide fragment of the myofilament protein or the peptide fragment of the covalent or non-covalent complex formation consists of: a skeletal troponin I peptide fragment, a skeletal myosin light chain 1 peptide fragment, a skeletal troponin T peptide fragment, a

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skeletal troponin C peptide fragment, or a skeletal  
 $\alpha$ -actinin peptide fragment.

In contrast, Löfberg et al. teach detecting skeletal muscle damage in rhabdomyolysis patients by detecting myosin heavy chain (MHC) fragments in serum. Further, all teachings in Löfberg et al. relating to detecting TnI and TnT relate to detecting cardiac TnI and cardiac TnT and cardiac damage associated with rhabdomyolysis and/or to exclude concomitant myocardial damage. See stated objective in Löfberg et al. at page 1211.

Accordingly, this reference which requires detection of myosin heavy chain to assess skeletal muscle damage cannot anticipate the instant claims drawn to detecting skeletal damage via detecting a peptide fragment or a covalent or non-covalent complex formation with a peptide fragment wherein the peptide fragment consists of a skeletal troponin I peptide fragment, a skeletal myosin light chain 1 peptide fragment, a skeletal troponin T peptide fragment, a skeletal troponin C peptide fragment, or a skeletal  $\alpha$ -actinin peptide fragment.

Withdrawal of this rejection under 35 U.S.C. 102(b) is therefore respectfully requested.

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IV. Rejection of Claims 56-59, 62-65, 68-69, 71-84 and 87-98 under 35 U.S.C. 102(b)

Claims 56-59, 62-65, 68-69, 71-84 and 87-98 have been rejected under 35 U.S.C. 102(b) as being anticipated by Wicks et al. (WO 94/27156). Applicants respectfully traverse this rejection.

At the outset, without conceding in any way to the Examiner's rejection, it is respectfully pointed out that claims 56-59, 62-65 and 71-79 have been canceled, without prejudice. Thus, this rejection as it pertains to these claims is now moot. Applicants reserve the right to pursue this subject matter in a continuation application.

Further claim 80, 97, 99, 100, 101 and 102 have been amended to state skeletal muscle damage and to specify skeletal peptide fragments in accordance with teachings throughout the specification. See, for example page 2, lines 20-25, page 4, lines 4-12, page 11, line 22, through page 12, line 3, page 12, lines 22-24, page 37-41 and Figure 11-14.

Accordingly, the pending claims are drawn to detecting skeletal muscle damage and skeletal peptide fragments.

In contrast, teachings of Wicks et al. relate to detecting cardiac muscle damage via detecting cardiac

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troponin I. Thus, this reference cannot anticipate the instant pending claims.

Withdrawal of this rejection under 35 U.S.C. 102(b) is therefore respectfully requested.

**V. Rejection of Claims 56, 62-66, 68-69 and 71-79 under 35 U.S.C. 102(b)**

Claims 56, 62-66, 68-69 and 71-79 have been rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al. (WO 96/10078).

It is respectfully pointed out, without conceding in anyway to this rejection, that claims 56-59, 62-66, 68-69 and 71-79 have been canceled, without prejudice. Thus, this rejection is now moot. Withdrawal of this rejection is therefore respectfully requested.

**VI. Rejection of Claims 56-59, 62-65, 68-69, 71-84, 87-90 and 92-98 under 35 U.S.C. 102(b)**

Claims 56-59, 62-65, 68-69, 71-84, 87-90 and 92-98 have been rejected under 35 U.S.C. 102(b) as being anticipated by Westfall et al.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out without conceding in anyway to this rejection that claims 56-59, 62-65 and 71-79 have been canceled, without prejudice. Thus,

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this rejection as it pertains to these claims is now moot.

Further claims 80, 97 and 99-102 have been amended to state skeletal muscle damage and to specify skeletal peptides in accordance with teachings throughout the specification. See, for example page 2, lines 20-25, page 4, lines 4-12, page 11, line 22, through page 12, line 3, page 12, lines 22-24, page 37-41 and Figure 11-14.

Accordingly, the pending claims are drawn to detecting skeletal muscle damage and skeletal peptides.

In contrast, teachings of Westfall et al. relate to detecting cardiac muscle damage. Thus, this reference cannot anticipate the instant pending claims.

Withdrawal of this rejection under 35 U.S.C. 102(b) is therefore respectfully requested.

#### VII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

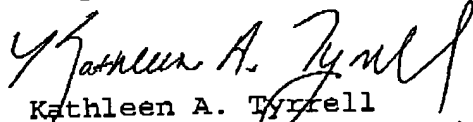
In the event that the amendments and arguments presented herein do not place this application in condition for allowance, the courtesy of an interview with the



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Examiner is respectfully requested prior to issuance of any  
Final Rejection.

Respectfully submitted,

  
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